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TISSUE SPECIMEN ISOLATING AND DAMAGING DEVICE AND METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to treatment of tissue specimens and, more specifically, to the treatment of the tissue specimens *in vivo*.

2. Description of the Related Art

The prior art discloses devices and methods of isolating a tissue specimen while it remains in surrounding tissue. The prior art also discloses devices and methods of ablating or otherwise damaging a non-isolated tissue specimen *in vivo*. However, the prior art does not disclose, suggest, nor motivate combining the two concepts into one method or device. Additionally, the prior art does not disclose any synergistic effects of combining the two concepts.

It is disclosed in a paper entitled "The Loop Electrode: A New Device For US-guided Interstitial Tissue Ablation Using Radiofrequency Electrosurgery - An Animal Study," T. Lorentzen et al., Min Invas Ther & Allied Technol 1996: 5: 511-516, that a radiofrequency loop is used to perform interstitial tissue ablation. The device was inserted into calf livers and rotated to interstitially cut off lesions. The paper reviews minimally invasive tissue ablation techniques, such as intraoperative cryosurgery and percutaneous methods such as laser, microwaves, radiofrequency electrosurgery, and injection of ethanol or hot saline. The paper also reviews high-focused ultrasound as an example of a non-invasive method. The paper does not disclose, suggest, nor motivate combining the use of a radiofrequency loop with other tissue ablation methods.

A procedure is disclosed in a paper entitled "Interstitial Hyperthermia Of Colorectal Liver Metastases With A US-guided Nd-YAG Laser with a Diffuser Tip: A Pilot Clinical Study," C. Nolsøe et al., Radiology, 1993; 187:333-337, that

involves placing a laser fiber in the center of a tumor and irradiating the tumor to achieve hyperthermia ablation. It is also disclosed to use ultrasound to monitor the temperature of the tumor during the method. The paper discloses a charred border region about the tissue specimen and a coagulated region beyond the charred border. The paper does not disclose any concerns associated with ablating a non-isolated tissue specimen. The paper does not disclose, suggest, nor motivate combining the use of lasers with other tissue ablation methods.

It is disclosed in a paper entitled "Phototherapy of Tumors," S.G. Brown, World J. Surg. 7, 700-709, 1983, the use of the chemical hematoporphyrin derivative (HpD) in conjunction with a dye laser for tumor therapy. The HpD/dye laser method is not thermal, as is the case with most laser methods, but depends on the production of singlet oxygen by activated HpD. The paper discloses the promise of the HpD/dye laser methods - but with no disclosure, suggestion, or motivation to isolate the tissue specimen prior to treatment. The paper discloses the problems associated with unacceptable damage to surrounding tissue during thermal laser methods.

It is disclosed in a paper entitled "Clinical Thermochemotherapy: A Controlled Trial In Advanced Cancer Patients," F.K. Storm et al, Cancer 53:863-868, 1984, to combine hyperthermia and chemotherapy for increased drug uptake of cancer cells. The hyperthermia was administered using a magnetrode magnetic-loop induction device. The paper does disclose the beneficial of preserving the tissue surrounding the tissue specimen, which in the disclosed method is due to coincident vascular occlusion. It does not disclose, motivate, or suggest direct methods of severing vascular connections between a tissue specimen and surrounding tissue, in conjunction with other methods of tissue specimen ablation.

It is disclosed in a paper entitled "Liver Photocoagulation With Diode Laser (805nm) Vs Nd:YAG Laser (1064 nm)," S.L. Jacques et al., SPIE Vol. 1646 Laser-Tissue Interaction III (1992), p. 107-117, that laser treatment results in radially

expanding regions of tissue damage. The paper does not disclose, suggest, nor motivate isolating the tissue specimen targeted for necrosis and any result that may have with reducing damage to surrounding tissue.

It is disclosed in a paper entitled "MR Imaging Of Laser-Tissue Interactions," F.A. Jolesz, Radiology 1988; 168:249-253, that thermal transfer and damage to surrounding tissue during hyperthermia treatment should be monitored. The paper also discloses that circulatory cooling, among other parameters, affects energy deposition. The paper does not disclose, suggest, nor motivate that isolating the tissue specimen prior to hyperthermia treatment. This information is similarly disclosed in a paper entitled "Temperature Mapping With MR Imaging Of Molecular Diffusion: Application to Hyperthermia," D.L. Bihan, Radiology 1989; 171: 853-857.

Therefore, the prior art discloses damage occurs to tissue surrounding a tissue specimen to be treated. What is needed is a device and method for reducing damage to the surrounding tissue. What is also needed is a device and method with increased efficiency for damaging the tissue specimens.

SUMMARY OF THE INVENTION

In an aspect of the invention, a tissue specimen that is disposed in surrounding tissue is treated. The treatment comprises an isolation step and a damaging step. During the isolation step, the tissue specimen is isolated from the surrounding tissue by at least partially severing the tissue specimen from the surrounding tissue. Next, the tissue specimen is damaged.

In an aspect of the invention, the isolating step further comprises the step of moving a tissue specimen isolating tool about the tissue specimen. In a further aspect of the invention, the tissue specimen isolating tool comprises a radio frequency energized wire. The treatment process may include the step of applying a tool charged with radio frequency energy to the tissue specimen.

In aspects of the invention, the damaging step may comprises applying ionizing radiation to the tissue specimen, cutting the tissue specimen, thermally treating the tissue specimen, chemically treating the tissue specimen, or sealing an outer boundary of the tissue specimen.

In an aspect of the invention, a device for treatment of a tissue specimen in surrounding tissue comprises an operational portion, a tissue severing tool, and a tissue specimen damager. The tissue specimen isolating tool and the tissue specimen damager are disposed at the operational portion.

In a further aspect of the invention, a radio frequency generation source is functionally connected to the tissue specimen isolating tool.

In an aspect of the invention, the tissue specimen isolating tool of the treatment device comprises a cutting member that is extendable to an outwardly radially bowed position about the operational portion. In a further aspect of the invention, a cutting member radio frequency generation source is functionally connected to the cutting member.

In an aspect of the invention, the tissue specimen damager of the treatment device comprises at least one metal member extending from the operational portion and being functionally connectable to a metal member radio frequency generation source.

In aspects of the invention, the tissue specimen damager may comprise an ionizing radiation director, a tissue specimen cutter, a thermal treatment system, or a chemical introduction system.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a side view tissue specimen isolating and damaging device using radio frequency energized wires according to an embodiment of the invention;

Figure 2 shows a sectional view of the device of Figure 1 in a breast after isolation of the tissue specimen and prior damaging the tissue specimen;

Figure 3 shows the same sectional view as does Figure 2 but after damaging the tissue specimen by thermal treatment;

Figure 4 is a nonexclusive chart of treatment methods for damaging the tissue specimen according to embodiments of the invention; and

Figures 5-8 are side views of tissue specimen isolating and damaging devices according to various embodiments of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the figures, and specifically to Figure 1, a tissue specimen isolating and damaging device 10 comprises a wand 12 having a proximal end 14 shown to the right and a distal end 16 shown to the left. The device 10 is used to isolate a tissue specimen while the tissue specimen is disposed in surrounding tissue and then damage the tissue specimen (see Figures 2 and 3). The isolation step may encompass isolating the tissue specimen from circulation and/or may encompass generally severing of the tissue specimen from the surrounding tissue. After the damaging step, the tissue specimen may remain in the body, turn into fibrotic tissue, and/or be removed from the body during the process or at a later time.

While isolating the tissue specimen may result in necrosis, the device 10 damages the tissue specimen to insure necrosis occurs. The necrosis of the tissue specimen results in reducing or eliminating the transfer of malignant or diseased tissue from the tissue specimen. The necrosis of the tissue specimen also dissuades the patient's body from repairing the tissue specimen. The shown embodiment of the invention utilizes a radio frequency generator 18 to perform the procedure. Other embodiments of the invention may use other methods, examples of which are non-exclusively discussed below.

Located at the distal end 16 of the wand 12 is an operational portion 20 of the device 10. The operational portion 20 is involved with both isolating and damaging the tissue specimen. In the shown embodiment, an outwardly radially bowed wire 22 isolates the tissue specimen. The wire 22 is disposed at the operational portion 20 and rotationally connected to the wand 12. In the shown embodiment of the invention, the wire 22 is initially in a retracted position against the wand 12 (not shown) to reduce trauma to surrounding tissue during placement of the device 10. The wire 22 is extended outward radially after the operational portion 20 is disposed in or proximate to the tissue specimen.

The wire 22, which is a tissue specimen isolating tool of the device 10, is powered by the radio frequency generator 18 and rotated to isolate the tissue specimen. As the wire 22 is rotated, a periphery channel (see Figure 2) is formed between the tissue specimen and the surrounding tissue, thus severing the two. Other embodiments of the invention may have the wire 22 be fixedly and not rotatably connected to the wand 12, thus the whole wand is rotated to isolate the tissue specimen and not just the bowed wire 22.

Embodiments of the invention may comprise other tissue specimen isolating tools with cutting members, such as is disclosed in commonly assigned U.S. Patent Applications to Burbank et al. entitled "Breast Biopsy System and Method," USSN 09/057,303 and "Biological Tissue Specimen Encapsulation Device and Method Thereof," USSN 09/208,535, both of which are herein incorporated by reference in their entireties. Embodiments of the invention may only partially sever the tissue specimen from the surrounding tissue.

At the distal end 16 is a radio frequency wire 24 that is energized during the step of inserting the wand 12 into the surrounding tissue. Other embodiments may have other means for inserting the wand into the surrounding tissue, such as a non-energized piercing tool or some other form of energized piercing tool. Still other

embodiments of the invention may not have a piercing tool at the distal end 16, but rather enter the surrounding tissue through a pre-existing passage.

In the shown embodiment, the tissue specimen is ablated or otherwise damaged after isolation (see Figure 3). The damaging of the tissue sample results in necrosis. The damage may be caused by ionizing radiation that disrupts cellular functions. The tissue specimen may be damaged through mechanical means, such as cutting or otherwise morcellating the tissue specimen. Tissue specimen damage may be the result of thermal or chemical treatment.

Continuing to refer to Figure 1, radio frequency wires 28 that extend from the operational portion 20 of the device 10 are used to damage the tissue specimen. The wires 28 are initially in a retracted position in wand 12 or disposed on the wand 12. Either before, during, or after the isolation of the tissue specimen, the wires 28 are extended as shown and enter the tissue specimen. In a preferred embodiment of the invention, the wires 28 are disposed in the wand 12 and are extended prior to isolation of the tissue specimen. The extended wires 28 anchor the device 10 in the tissue specimen, resulting in a more precise isolation of the specimen. Other embodiments of the invention may have other methods or mechanisms for anchoring the device 10 in the tissue specimen.

The radio frequency wires 28, which comprise the tissue specimen damager of device 10, are shown extending toward the distal end 16 of the wand 12. Other embodiments of the invention may have wires 28 extending in any suitable direction. The wires 28 are shown extending almost to the radially bowed wire 22, resulting in the wires 28 being distributed throughout the tissue specimen. Other embodiments of the invention may have the wires 28 extending into a portion of the tissue specimen.

When energized, the radio frequency wires 28 damage the tissue specimen by causing the water molecules in the tissue specimen to vibrate and rapidly vaporize. The rapid vaporization results in the destruction of cells in the tissue

specimen, thus damaging the specimen. The rapid vaporization is a form of thermal treatment. The radio frequency wires may be mono- or bi-polar.

After treatment, the wires 28 may be retracted into the wand 12. Other embodiments of the invention may not have the wires 28 being retracted, but rather the wires 28 remain extended and slide out of the tissue specimen during removal of the wand 12 from the surrounding tissue. The distally leaning wires 28 facilitate their sliding out of the tissue specimen during wand removal.

The severing and isolation of the tissue specimen results in a more controlled and simpler process to damage the specimen. In the case of thermal treatment, a non-isolated tissue specimen is cooled or heated by blood circulating through the specimen. The thermal treatment of an isolated tissue specimen is not competing with the cooling or heating effects of blood circulation. Without competing with the effects of blood circulation through the specimen, the thermal treatment is shorter and more restricted to the immediate tissue specimen. Further, the isolation reduces thermal damage to the surrounding tissue.

Functionally connected to the proximal end 14 of the wand 12 is a control system 30. In the shown embodiment, the control system 30 manipulates the cutting wire 22 and the radio frequency wires 28. In some embodiments of the invention, the control system 30 may control the insertion and removal of the wand 12 from the tissue specimen and the surrounding tissue. The control system 30 is functionally connected to the radio frequency generator 18 that supplies energy to the wires 22 and 28. In the embodiments of the invention in which the radially bowed wire 22 is in a fixed position on the wand 12, the control system 30 rotates the wand 12 to isolate the tissue specimen. In other embodiments of the invention, the components of the device are manipulated by hand.

Referring now to Figure 2, the device 10 is shown disposed in a breast 50 with the operational portion 20 being disposed in a tissue specimen 52. In this embodiment, the breast 50 may be considered the surrounding tissue. The tissue

specimen 52 contains a tumor 54, which is shown cross-hatched. The cutting wire 22 is shown in the outwardly radially bowed position. The cutting wire 22 has already been rotated, thereby forming a periphery channel 56 and isolating the tissue specimen 52. Note the radio frequency wires 28 are not shown extended in Figure 2. In a preferred embodiment of the invention, the wires 28 are extended into the tissue specimen 52 prior to isolation.

Referring now to Figure 3, the tissue specimen 52 of Figure 2 has been damaged, resulting in damaged tissue specimen 60 through thermal treatment by the device 10. The radio frequency wires 28 of the device 10 are shown extended into the tissue specimen 60. The wires 28 had been energized, resulting in the vaporization of the water molecules, disruption of the cells of the tissue specimen, heating the specimen, and the ultimate damaging of it. The amount and time of the treatment may be predetermined or the device may comprise a feed back system (not shown) that indicates when the treatment has been completed. In a further step, the device 10 is removed from the breast 50, either without or without retracting the radio frequency wires 28 into the device 10.

Referring now to Figure 4, Chart 100 is a non-exclusive list of possible methods for damaging the *in vivo* tissue specimen besides thermal treatment through radio frequency devices. Listed as forms of thermal treatments 102 are laser, hot fluids, cold fluids, radio frequency energy and other electrosurgery techniques, microwave, focussed ultrasound, mechanical ultrasound, shock waves, resistive heating, cryosurgery using liquid or gas, cauterizing, and the application of a heated object. An example of a heated object is disclosed in U.S. Patent No. 4773413 to Hussein et al. entitled "Localized Heat Applying Medical Device," which is incorporated herein by referenced in its entirety. Other embodiments of the invention may use any suitable thermal treatment system to damage the tissue specimen.

The mechanical treatment list 104 includes morcellators and other cutting devices. The ionizing radiation treatment list 106 includes treatment with x-rays, including x-ray needles, gamma rays, and Brachytherapy seeds, which are forms of ionizing radiation directors. The chemical treatment list 108 includes treatment with ethanol, sotradechol, an acid, a base, various chemical compounds, various chemical mixtures, a catalyst, a sealing agent that seals the outside of the tissue specimen, and a photoreactive chemical that is used in conjunction with a light or laser system. Other embodiments of the invention may use any suitable chemical treatment system to damage the tissue specimen.

Referring now to Figure 5, a tissue specimen isolating and damaging device 200 has a laser device 202 at an operational portion 204. The laser device 202 damages a tissue specimen through thermal treatment. The shown embodiment of the invention has two outwardly radially bowed cutting wires 206. Embodiments of the invention may have one or more cutting wires 206 regardless of the treatment to damage the tissue specimen. Note that a cutting tip 210 is located at a distal end 212 of the device 200.

Referring now to Figure 6, a tissue specimen isolating and damaging device 220 has a morcellator 222 at an operational portion 224. The morcellator 222 is used to morcellate a tissue specimen. The tissue specimen may be morcellated after encapsulation of the tissue specimen. Encapsulation of the tissue specimen is disclosed in the previously referenced and incorporated U.S. Patent Application entitled "Biological Tissue Specimen Encapsulation Device and Method Thereof." The tissue specimen may be encapsulated with non-biodegradable or biodegradable material. Note that there is not a piercing tool on this embodiment of the invention. Other morcellating devices may have a piercing tool. Also note that the cutting wire is in a retracted position and not visible.

In an embodiment of the invention, the tissue specimen is damaged by encapsulation. The damage is the result of the tissue specimen being physically

isolated from the surrounding tissue. In an embodiment of the invention, a sheath may at least partially surround the tissue specimen (not shown). In another embodiment of the invention (not shown), the tissue specimen may be physically isolated by encapsulation accomplished with a chemical that flows into the periphery channel about the tissue specimen and seals specimen's outside surface. Suitable techniques known in the art for ensuring a continuous distribution of the sealing chemical may be employed, such as pressurizing the periphery channel.

Now referring to Figure 7, a tissue specimen isolating and damaging device 240 has outlets 242 at the operational portion 244. The outlets 242 permit the flow of a chemical into the tissue specimen, thus transforming the tissue specimen through a chemical reaction or other chemical treatment. The isolation of the tissue specimen reduces the amount of chemicals transferring to the surrounding tissue.

In other embodiments of the invention, hollow needles may extend from the operational portion 244 such that the chemical may be injected into the tissue specimen through the needles. Other embodiments of the invention may include slicing tools that make slits in the surface of the tissue specimen that is in contact with the wand 246. The slits facilitate infusion of the chemical. The slits may also be made by the cutting wire 248. The cutting wire 248 is rotated and partially extended into the tissue specimen at periodic intervals either before or after the tissue specimen has been isolated.

Referring now to Figure 8, a tissue specimen isolating and damaging device 260 cryogenically treats the tissue specimen 262 disposed at the operational portion 264 of the wand 266. A cryogenic fluid is flowed to the operational portion 264 through a feed line 268 and is returned to the control system (not shown) via a return line 270, both of which is disposed in the wand 266. The tissue specimen 262 is frozen and damaged through thermal treatment with the cryogenic fluid.

Embodiments of the invention have suitable control systems incorporated into the tissue specimen isolating and damaging device. Further, the embodiments

of the invention are suitably configured for different treatment methods and different tissue specimen shapes and sizes.

Although presently preferred embodiments of the present invention have been described in detail hereinabove, it should be clearly understood that many variations and/or modifications of the basic inventive concepts herein taught, which may appear to those skilled in the pertinent art, will still fall within the spirit and scope of the present invention, as defined in the appended claims.